

105TH CONGRESS
1ST SESSION

H. R. 524

To require the mandatory reporting of deaths resulting from the prescribing, dispensing, and administration of drugs, to allow the continuation of voluntary reporting programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 4, 1997

Mr. COYNE introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To require the mandatory reporting of deaths resulting from the prescribing, dispensing, and administration of drugs, to allow the continuation of voluntary reporting programs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE AND PURPOSE.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Safe Medications Act of 1997”.

6 (b) PURPOSE.—It is the purpose of this Act to have
7 the Secretary of Health and Human Services create a data

1 bank for reports of deaths from the prescribing, dispens-
2 ing, and administration of drugs, to establish a program
3 using such data to assist in preventing such deaths, and
4 to educate and inform health care professionals of the
5 deaths that may occur in the course of drug therapy.

6 **SEC. 2. REPORTING.**

7 (a) IN GENERAL.—Any pharmacy, hospital, long-
8 term care facility, physician’s office, or other health care
9 facility, as defined by the Secretary of Health and Human
10 Services by regulation, in which a death occurs as a result
11 of the prescribing, dispensing, or administration of a drug
12 to an individual shall report such deaths to the Secretary
13 of Health and Human Services under section 3. Such a
14 report shall be made not later than 10 working days after
15 the date of the discovery of the deaths.

16 (b) REPORT REQUIREMENTS.—Each report of a
17 death from the prescribing, dispensing, or administration
18 of a drug to an individual shall at least contain—

19 (1) an identification of the person making the
20 report, including the address and telephone number
21 of such person, and the name and address of the fa-
22 cility in which the drug was prescribed, dispensed, or
23 administered;

1 (2) a description of the error in the prescrip-
2 tion, dispensing, or administration of the drug if an
3 error occurred to include the following:

4 (A) the misunderstanding (if any) of an
5 oral communication for the prescription of the
6 drug involved,

7 (B) the misinterpretation or misreading (if
8 any) of a written prescription for the drug in-
9 volved,

10 (C) the improper identification (if any) of
11 the drug involved because of shelf placement,

12 (D) the confusion (if any) over the drug
13 involved because of product packaging or drug
14 name, and

15 (E) when and how the error was discov-
16 ered;

17 (3) the brand name of the drug involved (if
18 any), the generic name of such drug, the manufac-
19 turers of such drug, the labeler of such drug if dif-
20 ferent from the manufacturer, the dosage form of
21 such drug, the strength of such drug, and the type
22 and size of the drug containers;

23 (4) the lot number of the drug involved, if avail-
24 able;

1 (5) information on the patient for whom the
2 drug involved was prescribed, dispensed, or adminis-
3 tered, including the patient's age and sex;

4 (6) the diagnosis for which the drug involved
5 was prescribed, dispensed, or administered; and

6 (7) the date and time of the death.

7 Reporting requirements shall be updated as directed by
8 the Secretary.

9 **SEC. 3. DATA BANK.**

10 (a) **ESTABLISHMENT.**—The Secretary of Health and
11 Human Services shall establish and maintain in coopera-
12 tion with the compiler of the official compendia of drug
13 standards a data bank to receive reports under section 2
14 of deaths. If such compiler will not cooperate in connection
15 with such data bank, the Secretary shall establish or by
16 contract provide for such data bank.

17 (b) **SECRETARIAL ACTION.**—The Secretary shall re-
18 view information reported to the data bank on an ongoing
19 basis to determine trends relating to drugs and shall re-
20 port such information to the compiler of the official com-
21 pendia of drug standards on an ongoing basis for consider-
22 ation of revision of the packaging and labeling require-
23 ments or other standards for drugs for dissemination to
24 physicians, pharmacists, and other health professionals in-
25 volved in the prescribing, dispensing, and administration

1 of drugs to patients. Such reporting of aggregate data
2 shall be done in a manner which assists such health pro-
3 fessionals in identifying and reducing patterns and inci-
4 dents of inappropriate use associated with certain drugs.

5 (c) CONFIDENTIALITY.—The identity of a person
6 making a report to the data bank, the deceased, and the
7 individual who prescribed, dispensed, or administered the
8 drug shall be considered as privileged and confidential in-
9 formation for purposes of any law requiring disclosure of
10 information.

11 (d) SHARED INFORMATION.—The Secretary shall
12 share the reported information with governmental licens-
13 ing, accreditation, and inspection agencies for their action
14 with the appropriate organizations to ensure that there
15 has not been a failure to report such deaths.

16 (e) ENFORCEMENT.—Whoever with false pretenses
17 reports to the data bank, requests information from the
18 data bank, or unlawfully gains access to the data bank
19 shall be fined not more than \$15,000 or imprisoned for
20 not more than 3 years, or both, except that if a person
21 commits a violation of this subsection after a conviction
22 for a violation of this subsection has become final, such
23 person shall be fined not more than \$25,000 or imprisoned
24 for not more than 3 years, or both.

1 **SEC. 4. PENALTIES.**

2 (a) IMPOSITION OF FINE.—Any institution that does
3 not make a report as required by section 2 shall be subject
4 to a fine of \$15,000 for each report not made. Within 60
5 days of a conviction under this subsection, a person shall
6 submit to the Secretary of Health and Human Services
7 a plan for the reporting to the data bank of deaths from
8 drugs and drug prescribing, dispensing, and administra-
9 tion errors.

10 (b) MANDATORY EXCLUSION FROM MEDICARE AND
11 STATE HEALTH CARE PROGRAMS.—Section 1128(a) of
12 the Social Security Act (42 U.S.C. 1320a–7(a)) is amend-
13 ed by adding at the end the following new paragraph:

14 “(5) FAILURE TO REPORT DEATHS RESULTING
15 FROM THE PRESCRIBING, DISPENSING, AND ADMIN-
16 ISTRATION OF DRUGS.—Any individual or entity that
17 has failed or refused to respond to a subpoena for
18 information on a reportable incident or has failed to
19 meet the requirements of section 2 of the Safe Medi-
20 cations Act of 1997.”.

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